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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,211	10/30/2006	Bakulesh Mafatlal Khmar	21059/0206916-US0	9175
7278 7590 06/08/2010 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 06/08/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,211	<b>Applicant(s)</b> KHAMAR, BAKULESH MAFATLAL	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-29,32,34,36-43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48 is/are allowed.
- 6) ☒ Claim(s) 22-29,32,34,36-43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

#### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2009 has been entered.

Claims 22, 23, 24, 25, 28, 29, 32, 34, 45, 46, 47 and 48 have been amended. Claims 30, 31, 33, 35 and 44 have been cancelled.

2. Claims 22-29, 32, 34, 36-43 and 45-48 are pending and under consideration.

#### **Rejections Moot or Withdrawn**

3. The rejection of claims 30, 31, 33, 35 and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot in light of the cancellation of the claims.

4. The rejection of claims 28, 29, 45, 46, 47, and 48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in light of the amendments of the claims.

#### **Rejections Maintained**

5. The rejection of claims 22-27, 32, 34 and 36-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Applicant argues that the amendment of the claims obviates the rejection because the type of composition is specified as: 1) heat killed whole cell *Mycobacterium w*, 2) sonicated *Mycobacterium w*, 3) a solvent extract of *Mycobacterium w*, wherein the solvent is selected

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from a group of 9 solvents, or, 4) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase or pronase. The examples in the specification and the Declaration provide support for the compositions.

The examiner has considered applicant's arguments and amendments of the claims and finds it persuasive for compositions of either heat killed whole cell *Mycobacterium w* or sonicated *Mycobacterium w*. However, the examiner does not find it persuasive for either a solvent extract of *Mycobacterium w*, wherein the solvent is selected from a group of 9 solvents, or, an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase or pronase.

The listing of extracts by solvent, pages 5-8, indicates only chloroform, ethanol, methanol and acetone. No extracts are listed using phenol, isopropyl alcohol, acetic acid, urea, or hexane.

The listing of extracts by enzymatic treatment only indicates liticase. No extracts are listed using pronase.

Therefore, the rejection is maintained for embodiments of solvent extracts using phenol, isopropyl alcohol, acetic acid, urea, or hexane, and enzymatic extracts using pronase.

#### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 45, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from claim 22.

Newly amended Claim 22 recites a pharmaceutical composition comprising an effective amount of: 1) heat killed whole cell *Mycobacterium w*, 2) sonicated *Mycobacterium w*, 3) a solvent extract of *Mycobacterium w*, wherein the solvent is selected from a group of 9 solvents, or, 4) an enzymatic extraction of *Mycobacterium w*, wherein the enzyme is selected from liticase or pronase.

Claim 45, 46 and 47 recite that the pharmaceutical composition is in a unit dosage of *Mycobacterium w*, not heat killed whole cell *Mycobacterium w*. It is unclear if the composition in the instant claims is or is not heat killed whole cell *Mycobacterium w*. Proper designation is required.

8. Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from a rejected claim.

#### **Conclusion**

9. Claims 22-29, 32, 34, 36-43 and 45-47 are rejected.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

July 16, 2009